

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KATO, et al.

Serial No.: 10/506,335

Group Art Unit: 1619

Filed: September 2, 2004

Examiner: GULLEDGE, B.R.

For: Whitening Cosmetic Composition

DECLARATION UNDER 37 CFR §1.132

I, Eiko KATO, hereby declare and state that:

I am a citizen of Japan, residing at Chuo-ku, Chiba-shi, Chiba.

2. I work in the section of Show Denko Co., Ltd., in which research and development related to the present invention were performed. I am fully familiar with the subject matter of the present application as well as the references relied upon by the Examiner in the prosecution of this application.

3. I obtained a bachelor's degree from Japan Woman's University, department of chemical and biological Sciences, in March 1989, where I studied plant physiology.

4. I am currently employed by Showa Denko Co., Ltd., and began working for Showa Denko Co., Ltd., in April 1989, where I have engaged in research and development relating to functional chemicals.

5. I have conducted the comparative tests described below.

### **Object of Test**

To evaluate effects of preventing pigmentation by tocopherol or its derivatives, and to compare the results thereof with the effect of preventing pigmentation by tocopherol alkylglycine ester or its salts evaluated in Example 5 of the original specification of the present application.

### **Experiments and Evaluation**

Eight kinds of lotions with components and their contents as shown in the table below were prepared. Each of the lotions was evaluated for prevention of pigmentation as in Example 5 of the original specification of the present invention.

Specifically, hair on the entire surface of the back of each of 15 male Wistar-Kyoto guinea pigs (WK, SPF) was cut by means of electric hair clippers (0.05 mm blade), was subsequently shaved by means of an electric shaver, followed by covering with an adhesive stretch bandage (SILKYTEX, covered the outside thereof with an aluminum foil) wherein 6 holes of 1.5 cm X 1.5 cm had been formed.

Subsequently, the animal was held by a retainer, followed by exposure of UV rays having medium wavelength (UVB) of  $750 \text{ mJ/cm}^2$  to each part from a distance of approximately 10 cm by means of a UV exposure apparatus (Shinano Co., Ltd., Toshiba FL40S/E30 model fluorescent lamp, equipped with six SE lamps).

From 4 days after the exposure to 28 days, each product of the Lotions a. to i. in an amount of 0.05 ml was successively applied to 10 holes twice a day, that is in the morning and in the evening.

Twenty-eight days after the exposure, the strength of pigmentation was evaluated by evaluation points according to the evaluation criteria described below. The effects of preventing pigmentation were evaluated by the average value obtained from the evaluation points (10 data), and are shown in the following table.

	Lotion ID.	a	b	c	d	e	f	g	h	i
Tocopherol and its derivatives	dl- $\alpha$ -tocopherol	2.0	-	-	-	0.1	-	-	-	-
	dl- $\gamma$ -tocopherol	-	2.0	-	-	-	0.1	-	-	-
	dl- $\delta$ -tocopherol	-	-	2.0	-	-	-	0.1	-	-
	tocopherol acetate	-	-	-	2.0	-	-	-	0.1	-
Ethanol <sup>1)</sup>		70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0
Propylene glycol		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Methyl p-hydroxybenzoate		0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Purified water		balance	balance	balance	balance	balance	balance	balance	balance	Balance
Evaluation (average)		3.4	3.0	3.2	3.4	3.6	3.3	3.4	3.5	3.6

1) Compared to the lotions in the examples of the specification of the present application, the amount of ethanol was increased to obtain homogeneous lotions. The tocopherols and their derivatives contained the above lotions in this experiment are oil-soluble.

#### Evaluation Criteria

No pigmentation is observed	evaluation point 0
Very slight pigmentation is observed	evaluation point 1
Slight pigmentation is observed	evaluation point 2
Fair degree of pigmentation is observed	evaluation point 3
Strong pigmentation is observed	evaluation point 4

**Conclusion**

As shown in Table, Lotions a. to d., which contain 2.0 wt% of either dl- $\alpha$ -tocopherol, dl- $\gamma$ -tocopherol, or dl- $\delta$ -tocopherol, have evaluation points (average) between 3.0 and 3.4; while Lotions e. to h., which contains 0.1 wt% of either of them, have evaluation points (average) between 3.3 and 3.6. Lotion i., which does not contain dl- $\alpha$ -tocopherol, dl- $\gamma$ -tocopherol, or dl- $\delta$ -tocopherol, has evaluation point (average) of 3.6.

In contrast to these results, Lotion 1 to 4 evaluated in Example 5 of the original specification of the present application, which contain 2.0 wt % of tocopherol dimethylglycine ester hydrochloride, have evaluation points (average) between 2.0 to 2.2; and Lotion 7 to 10, which contain 1.0 wt % of them have evaluation points (average) between 3.0.

Based on these comparisons, it has become clear that the tocopherol dimethylglycine ester hydrochloride has effects of preventing pigmentation superior to that of other compounds.

6. I understand fully the content of this declaration.

7. I, Eiko KATO, the undersigned declarant declares further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18 of

the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Sept/4/2009

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Eiko Kato